IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES, *et al.*, *Plaintiffs*, *ex rel.* JEROME PALMIERI, *Relator*, v. ALPHARMA, INC., *et al.*, *Defendants*.	Civil Action No. ELH-10-1601

MEMORANDUM OPINION

Jerome Palmieri, the relator, filed this *qui tam* action on behalf of the United States of America and various individual states (collectively, the "*Qui Tam* States")[1] against his employers, Alpharma, Inc. and Alpharma Pharmaceuticals, LLC (collectively, "Alpharma"); King Pharmaceuticals, Inc. ("King"); and Pfizer, Inc. ("Pfizer"), defendants,[2] pursuant to the False Claims Act ("FCA"), 31 U.S.C. §§ 3729 *et seq*. and analogous state statutes of the *Qui Tam* States. These statutes permit a private party, as relator, to sue on behalf of the government to recover damages against defendants who have caused fraudulent claims for payment to be submitted against the public fisc. As an incentive to bring such suits, a successful relator is entitled to share in the government's recovery from the defendants. *See generally ACLU v.*

[1] The "*Qui Tam* States" are California; Delaware; Florida; Georgia; Hawaii; Illinois; Indiana; Louisiana; Michigan; Montana; Nevada; New Hampshire; New Jersey; New Mexico; New York; Oklahoma; Rhode Island; Tennessee; Texas; and Wisconsin; the Commonwealths of Massachusetts and Virginia; and the District of Columbia.

[2] Alpharma Pharmaceuticals, LLC is a subsidiary of Alpharma, Inc. Through a merger between Alpharma and one of King's subsidiaries, Alpharma became a wholly owned subsidiary of King in December 2008. In October 2010, King merged with Pfizer. *See* Complaint ¶¶ 25-27.

Holder, 673 F.3d 245, 246-51 (4th Cir. 2011) (describing history and current provisions of FCA).[3]

This suit concerns defendants' marketing of Flector Patch, a topical pain medication delivered by a transdermal patch, which was approved by the United States Food and Drug Administration ("FDA") for the treatment of "'acute pain due to minor strains, sprains, and contusions.'" Complaint ¶ 125 (citation omitted). Federal and state health care programs, such as Medicaid and Medicare, that pay for prescription medications generally do not permit reimbursement for a medication that is prescribed for a so-called "off-label" use—*i.e.*, a use other than the use for which the medication has been approved by the FDA. Mr. Palmieri alleges that defendants engaged in a program of aggressive and illegal marketing of Flector Patch to physicians. The alleged marketing program encouraged physicians, sometimes by way of unlawful "kickbacks," to prescribe Flector Patch to their patients, including prescriptions for off-label uses and at excessive dosages. According to the relator, some of the resulting off-label, excessive, or unlawfully-induced prescriptions of Flector Patch were submitted to federal and state government agencies for reimbursement.

The relator filed his Complaint (ECF 2) on April 20, 2010,[4] under seal, pursuant to the initial sealing provisions of the FCA, in order to provide time to the United States and the *Qui*

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[3] In addition to ordinary federal question jurisdiction, *see* 28 U.S.C. § 1331, the FCA contains a specific grant of subject matter jurisdiction to the federal district courts. *See* 31 U.S.C. § 3732(a). Moreover, a district court with jurisdiction under the FCA also has jurisdiction as to state-law *qui tam* claims "aris[ing] from the same transaction or occurrence." *Id.* § 3732(b).

[4] Mr. Palmieri initially filed suit in the United States District Court for the Eastern District of Pennsylvania. Only Alpharma and King were named as defendants in the original Complaint. The United States moved to transfer venue, pursuant to 28 U.S.C. § 1404(a). The

Tam States to decide whether they wished to intervene. *See* 31 U.S.C. § 3730(b)(2).[5] None of the governmental plaintiffs intervened, and the suit was unsealed on July 5, 2011. *See* ECF 20. On October 25, 2011, the relator filed an Amended Complaint (ECF 43), which is the operative pleading.

Defendants have moved to dismiss (ECF 70), arguing that a provision of the FCA known as the "first-to-file" rule precludes this Court from exercising subject matter jurisdiction. In the alternative, they contend that the Amended Complaint fails to state a claim on which relief can be granted, in light of the heightened pleading requirements applicable to fraud claims under Fed. R. Civ. P. 9(b). In their view, the Amended Complaint does not identify any specific instance in which a particular false claim was submitted to the government.

The relator has filed an Opposition (ECF 71), and defendants have filed a Reply (ECF 72). No hearing is necessary to resolve the issues. *See* Local Rule 105.6. For the reasons that follow, I will grant the Motion. In particular, I conclude that the Court possesses subject matter jurisdiction, but that the Amended Complaint fails to state a claim upon which relief can be granted under the Rule 9(b) standard, as articulated by the Fourth Circuit.

Background[6]

Defendants manufacture and market Flector Patch, a transdermal patch that delivers, via absorption through the patient's skin, a topical application of 1.3% diclofenac epolamine. *See*

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relator did not object and the suit was transferred to this district on or about June 11, 2010. In this Court, the case was reassigned from Judge Catherine C. Blake to me on January 13, 2011.

[5] The analogous *qui tam* statutes of the *Qui Tam* States also provide for initial filing of a *qui tam* complaint under seal, in order to permit the state to investigate the claim and determine whether it wishes to intervene.

[6] The factual summary is derived from the relator's 110-page Amended Complaint.

Amended Complaint ¶¶ 88-89. Diclofenac epolamine is a non-steroidal anti-inflammatory drug ("NSAID"), of the same family as ibuprofen and naproxen. *See id.* Flector Patch is the only prescription NSAID topical patch on the market. *Id.* ¶ 89.

The FDA approved Flector Patch for prescription use in December 2007, *id.* ¶ 92, as a "'topical treatment of acute pain due to minor strains, sprains, and contusions.'" *Id.* ¶ 94 (citation omitted in original). The use was approved for up to fourteen days. *Id.* ¶¶ 101, 114-15. Like other NSAIDs, Flector Patch entails risks of cardiovascular and gastrointestinal side effects that increase the longer the drug is used. *Id.* ¶ 91. Therefore, Flector Patch's FDA-approved label contains a warning that a patient should use only "'the lowest effective dose for the shortest duration consistent with individual treatment goals.'" *Id.* (citation omitted in original).

Notably, Flector Patch is marketed in Europe under the name "Flector Tissugel," and is approved in Europe for treatment of chronic pain and inflammatory conditions such as osteoarthritis, rheumatoid arthritis, menstrual pain, bursitis, ankylosing spondylitis, and tendonitis. *Id.* ¶ 99. However, defendants have not sought FDA approval in the United States for these indications. *Id.*

Mr. Palmieri, the relator, has been employed since 2001 as a sales representative for Alpharma (and later, King and Pfizer), to market defendants' prescription pain medications, including Flector Patch, to physicians who treat chronic pain. Amended Complaint ¶ 23. He alleges that defendants engaged in a comprehensive scheme to promote the prescription of Flector Patch for off-label uses and in excessive dosages.

It is salient that federal law does not prohibit a physician from prescribing an approved drug for a non-approved, or "off-label," use. *See* 21 U.S.C. § 396. However, "it is unlawful for

a manufacturer to introduce a drug into interstate commerce with an intent that it be used for an off-label purpose, and a manufacturer illegally 'misbrands' a drug if the drug's labeling includes information about its unapproved uses." *Washington Legal Found. v. Henney*, 202 F.3d 331, 332-33 (D.C. Cir. 2000) (citing statutes) (internal citations omitted). Furthermore, "a manufacturer's direct advertising or explicit promotion of a product's off-label uses is likely to provoke an FDA misbranding or 'intended use' enforcement action." *Id.* at 333; *see also* 21 C.F.R. § 202.1(e)(4)(ii) (stating that an advertisement for an FDA-approved prescription drug generally "may recommend and suggest the drug only for those uses contained in the [FDA-approved] labeling thereof"). Therefore, the relator contends that defendants' scheme to promote off-label use of Flector Patch was unlawful.

The alleged unlawful scheme had many facets, according to the relator. For one, defendants allegedly instructed their sales representatives to market Flector Patch aggressively to physicians, such as pain management specialists, rheumatologists, and neurologists, who by the nature of their specialties treated only chronic pain and not the acute, localized pain for which Flector Patch was approved. *See* Amended Complaint ¶¶ 189-96. In addition, defendants promoted Flector Patch for continuous, rather than short-term use. *See id.* ¶ 201. Defendants specifically promoted a 60-patch/30-day prescription as the standard, appropriate prescription for Flector Patch, despite its FDA approval for usage for up to fourteen days. *See id.* ¶¶ 201-17. Defendants instructed their sales representatives to discourage shorter prescriptions as "subtherapeutic," and to cease promotional efforts toward physicians, such as emergency room and urgent care physicians, who routinely treat patients for acute pain and who often resisted prescribing Flector Patch at the 60-patch level. *See id.* Defendants also marketed Flector Patch

as an alternative to other prescription medications that are only FDA-approved for the treatment of chronic pain. *See id.* ¶¶ 228-43.

Furthermore, Mr. Palmieri alleges that some of defendants' promotional activities with respect to Flector Patch violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). In pertinent part, the Anti-Kickback Statute provides criminal penalties for

> knowingly and willfully offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program.

Id. § 1320a-7b(b)(2)(A).

Specifically, the relator avers that defendants distributed benefits to physicians who were high prescribers of Flector Patch through membership in a "Flector Patch Speakers' Bureau" and "Flector Patch Speaker's Training" program, by which the physicians received paid speaking engagements and access to lucrative referral networks. *See* Amended Complaint ¶¶ 137-60. Mr. Palmieri also contends that defendants provided samples of Flector Patch to physicians in such a manner as to qualify as "inducements" under the Anti-Kickback Statute. *See id.* ¶¶ 161-81.

Although the relator contends that many of defendants' activities, summarized above, were unlawful, the activities would not, by themselves, violate the False Claims Act or its state law analogs. However, Mr. Palmieri also alleges that, by engaging in the conduct described above, defendants knowingly caused false claims to be presented to federal and state government health care programs, in the form of reimbursement claims for prescriptions for off-label uses or excessive dosages of Flector Patch. The presentment of such false claims for payment to government programs constitute the basis for *qui tam* liability.

Government funded health care programs generally do not pay for drugs that are prescribed for off-label uses. For instance, the Medicaid program funds healthcare for low-income persons through a combinaton of federal and state funding. Federal reimbursement for a prescription drug under Medicaid is limited, with some exceptions, to a drug prescribed for a use for which the drug has been approved by the FDA. *See* 42 U.S.C. § 1396r-8(k)(2)-(3), (6). Moreover, the relator alleges that most states, including the *Qui Tam* States, that provide state funds for reimbursement for prescription drugs under Medicaid limit coverage in the same way. *See* Amended Complaint ¶ 53. And, the same limitation applies to coverage for prescription drugs for the elderly and disabled under the Medicare Part D program. *See* 42 U.S.C. § 1395w-102(e)(4)(A)(ii) (incorporating § 1396r-8(k)(6) by cross-reference). Ordinarily, other programs that provide federal funding for healthcare also limit prescription drug coverage to usages approved by the FDA. *See* Amended Complaint ¶¶ 65-68. The relator contends that defendants caused off-label prescriptions for Flector Patch to be submitted for reimbursement to these government health care programs, thereby causing the presentment of false claims.

In addition, Mr. Palmieri's allegation that defendants violated the Anti-Kickback Statute constitutes another potential avenue to False Claims Act liability. In March 2010, as part of the Patient Protection and Affordable Care Act of 2010 ("PPACA"), Pub. L. No. 111-148, 124 Stat. 119 (Mar. 23, 2010), the Anti-Kickback Statute was amended to provide expressly that "a claim that includes items or services resulting from a violation of [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g) (as amended by § 6402 of PPACA). But, even before this express statutory amendment, some courts had recognized that a violation of the Anti-Kickback Statute could, under some

circumstances, form a predicate for FCA liability. *See, e.g., United States ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co.*, 147 F. Supp. 2d 39, 54 (D. Mass. 2001) ("In order for the antikickback violation to be transformed into an actionable FCA claim, the government must have conditioned payment of a claim upon the claimant's certification of compliance with the antikickback provision. That certification may be proven by evidence showing the claimant expressly agreed to abide by the law as a condition of payment. In the absence of an affirmative certification, some courts have found 'implied certification' by virtue of the defendant's participation in the federal program.") (internal citations omitted).

Nevertheless, of particular relevance to the Motion, the Amended Complaint does not identify any particular instance on which an off-label or excessive prescription for Flector Patch was submitted to a government health program for reimbursement. Nor does the Amended Complaint provide examples of any occasions on which any of the doctors to whom defendants allegedly gave illegal kickbacks prescribed Flector Patch to a patient covered by a government prescription coverage program. Instead, the relator's charges rely on a crucial factual inference: the Amended Complaint recounts the total volume of Flector Patch prescriptions submitted to Medicaid and Medicare since 2008, and the amounts of money paid in reimbursements for those prescriptions, *see* Amended Complaint ¶¶ 268-71, to suggest that at least some of these prescriptions must have been off-label, excessive, or illegally induced prescriptions resulting from defendants' alleged scheme.

Additional facts will be presented in the Discussion.

Discussion

As noted, defendants challenge the Amended Complaint on two grounds: the "first-to-file" rule and the Rule 9(b) heightened pleading standard. I consider each contention in turn.[7]

A. First-to-File

As to the first-to-file rule, defendants argue that this case is barred because another *qui tam* suit alleging essentially the same fraudulent scheme, *United States ex rel. Littlewood v. King Pharmaceuticals, Inc.*, Civ. No. ELH-10-973 (D. Md.), was filed four days before the original Complaint in this case.[8]

The FCA's "first-to-file" rule is codified in 31 U.S.C. § 3730(b)(5). It provides: "When a person brings [a false claims action], no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." The first-to-file rule was one of several amendments enacted in 1986 to the FCA that sought to achieve "the golden mean between adequate incentives for whistle-blowing insiders with genuinely valuable information and discouragement of opportunistic plaintiffs who have no significant information to contribute of their own." *United States ex rel. Springfield Terminal Ry. v. Quinn*, 14 F.3d 645, 650 (D.C. Cir. 1994); *see United States ex rel. LaCorte v. Wagner*, 185 F.3d 188, 191 (4th Cir. 1999) (stating that the 1986 amendments "struck a careful balance between encouraging citizens to report fraud and stifling parasitic lawsuits").

[7] Although defendants' challenges are based primarily on federal law, both sides agree that the relator's state law claims are governed by the same standards. *See* Motion at 30-31; Opposition at 29.

[8] It so happens that *Littlewood* was an action in this district, and I was the presiding judge. However, the first-to-file rule, by its text, is not limited to first-filed actions pending in the same court or before the same judge.

The Fourth Circuit has not addressed § 3730(b)(5) in the context of a new FCA suit filed after a related FCA suit has already been filed.[9] However, as the D.C. Circuit recently put it, the statutory "command is simple: as long as a first-filed complaint remains pending, no related complaint may be filed." *United States ex rel. Batiste v. SLM Corp.*, 659 F.3d 1204, 1210 (D.C. Cir. 2011). In other words, "if one person 'brings an action' then no one other than the Government may 'bring a related action' while the first is 'pending.'" *United States ex rel. Chovanec v. Apria Healthcare Gp. Inc.*, 606 F.3d 361, 362 (7th Cir. 2010) (quoting statute).

The first-to-file rule creates "an incentive for relators with valuable information to file—and file quickly." *In re Nat. Gas Royalties Qui Tam Litigation (CO_2 Appeals)*, 566 F.3d 856, 961 (10th Cir. 2009). In essence, it sets off "a race to the courthouse among those with knowledge of fraud." *Campbell v. Redding Med. Ctr.*, 421 F.3d 817, 821 (9th Cir. 2005). Under the rule, the *qui tam* relator who beats the latecomers to the courthouse door is freed from having to "share in . . . recovery with third parties who do no more than tack on additional factual allegations to the same essential claim." *Grynberg v. Koch Gateway Pipeline Co.*, 390 F.3d 1276, 1279 (10th Cir. 2004). Thus, the first-to-file rule "functions both to eliminate parasitic plaintiffs who piggyback off the claims of a prior relator, and to encourage legitimate relators to

[9] The Fourth Circuit considered the aspect of § 3730(b)(5) that prohibits intervention in a pending FCA suit by a private party in *LaCorte*, *supra*, 185 F.3d 188. There, the Court rejected the attempts of would-be intervenors to "sidestep" § 3730(b)(5), saying: "The application of section 3730(b)(5) to this case is straight forward. [The intervenors] are persons other than the government. Therefore, the statute on its face precludes them from intervening in this action." *Id.* at 191. However, *LaCorte* did not address the impact of § 3730(b)(5) on a successive, separate FCA suit. Moreover, the Supreme Court has never directly addressed § 3730(b)(5). *But see Graham County Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, ___, 130 S. Ct. 1396, 1417 n.11 (2010) (Sotomayor, J., dissenting) (observing that "the FCA's first-to-file provision, 31 U.S.C. § 3730(b)(5), reflects Congress' explicit policy choice to encourage prompt filing and, in turn, prompt recovery of defrauded funds by the United States").

file quickly by protecting the spoils of the first to bring a claim." *In re Nat. Gas Royalties*, 566 F.3d at 961. The rule also has the benefit of "'prevent[ing] a double recovery'" against the defendant. *United States ex rel. Precision Co. v. Koch Indus., Inc.*, 31 F.3d 1015, 1018 (10th Cir. 1994) (quoting *Erickson ex rel. United States v. Am. Inst. of Bio. Sci.*, 716 F. Supp. 908, 918 (E.D. Va. 1989)).[10]

1. Standard of Review

The federal courts consistently view the first-to-file rule as a jurisdictional bar. *See, e.g.*, *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 16 (1st Cir. 2009) (describing first-to-file rule as a "jurisdictional bar[ ] that limit[s] a district court's subject matter jurisdiction over qui tam actions"); *United States ex rel. Branch Consultants v. Allstate Ins. Co.*, 560 F.3d 371, 376-77 (5th Cir. 2009) ("Congress has placed a number of jurisdictional limits on the FCA's *qui tam* provisions, including § 3730(b)(5)'s first-to-file bar.[ ] Under this provision, if [the relator's] claim had already been filed by another, the district court lacked subject matter jurisdiction and was required to dismiss the action."); *Walburn v. Lockheed Martin Corp.*, 432 F.3d 966, 970 (6th Cir. 2005) (describing first-to-file rule as a "jurisdictional limitation[ ] on *qui tam* actions"); *Grynberg*, *supra*, 390 F.3d at 1278 (stating that § 3730(b)(5) "is a jurisdictional limit on the courts' power to hear certain duplicative qui tam suits"). Accordingly, as the vehicle

[10] Each of the false claims acts of the *Qui Tam* States also contains a first-to-file rule. *See* Cal. Gov't Code § 12652(c)(10); Del. Code Ann. tit. 6, § 1203(b)(5); Fla. Stat. Ann. § 68.083(7); Ga. Code Ann. § 49-4-168.2(c)(6); Haw. Rev. Stat. § 661-25(e); 740 Ill. Comp. Stat. § 175/4(b)(5); Ind. Code Ann. § 5-11-5.5-4(g); La. Rev. Stat. Ann. § 46:439.2(a)(3); Mich. Comp. Laws Ann. § 400.610a(4); Mont. Code Ann. § 17-8-406(7); Nev. Rev. Stat. Ann. § 357.080(2); N.H. Rev. Stat. Ann. § 167:61-c(II)(b); N.J. Stat. Ann. § 2A:32C-5(i); N.M. Stat. Ann. § 44-9-5(E); N.Y. State Fin. Law § 190(4); Okla. Stat. Ann. tit. 63, § 5053.2(B)(5); R.I. Gen. Laws Ann. § 9-1.1-4(b)(5); Tenn. Code Ann. § 4-18-104(c)(10); Tex. Hum. Res. Code Ann. § 36.106; Wis. Stat. Ann. § 20.931(5)(e); Mass. Gen. Laws Ann. ch. 12, § 5C(6); Va. Code Ann. § 8.01-216.5(E); D.C. Code § 2-381.03(b)(6).

for their first-to-file challenge, defendants have invoked Fed. R. Civ. P. 12(b)(1), which authorizes a motion to dismiss a complaint for lack of subject matter jurisdiction.

A test of subject matter jurisdiction under Rule 12(b)(1) may proceed "in one of two ways": either a facial challenge, asserting that the allegations pleaded in the complaint are insufficient to establish subject matter jurisdiction, or a factual challenge, asserting "'that the jurisdictional allegations of the complaint [are] not true,'" or that other facts, outside the four corners of the complaint, preclude the exercise of subject matter jurisdiction. *Kerns v. United States*, 585 F.3d 187, 192 (4th Cir. 2009) (citation omitted); *see also Buchanan v. Consol. Stores Corp.*, 125 F. Supp. 2d 730, 736 (D. Md. 2001). This case presents a factual challenge. As indicated, defendants contend that the *Littlewood* action bars the instant suit.

In a factual challenge to subject matter jurisdiction, "the plaintiff bears the burden of proving" that subject matter jurisdiction is satisfied "by a preponderance of the evidence." *United States ex rel. Vuyyuru v. Jadhav*, 555 F.3d 337, 347 (4th Cir. 2009). In that circumstance, the court "may regard the pleadings as mere evidence on the issue and may consider evidence outside the pleadings without converting the proceeding to one for summary judgment." *Velasco v. Gov't of Indonesia*, 370 F.3d 392, 398 (4th Cir. 2004). Moreover, the district court is "entitled to decide disputed issues of fact with respect to subject matter jurisdiction," *Kerns*, 585 F.3d at 192, "[u]nless 'the jurisdictional facts are intertwined with the facts central to the merits of the dispute.'" *Vuyyuru*, 555 F.3d at 348 (citation omitted). "[T]he district court may . . . resolve the jurisdictional facts in dispute by considering evidence . . . such as affidavits." *Id.* When appropriate, the court may also "hold an evidentiary hearing to determine whether the facts

support the jurisdictional allegations." *United States v. North Carolina*, 180 F.3d 574, 580 (4th Cir. 1999); *accord Kerns*, 585 F.3d at 192.

Here, neither side has requested an evidentiary hearing, and no hearing is necessary. Whether the first-to-file rule bars this case depends on a comparison of the date and content of the pleadings in this case with the date and content of the pleadings in *Littlewood*. *See, e.g.*, *In re Nat. Gas Royalties*, *supra*, 566 F.3d at 964 ("The first-to-file bar is designed to be quickly and easily determinable, simply requiring a side-by-side comparison of the complaints."); *see also Anderson v. Fed. Deposit Ins. Corp.*, 918 F.2d 1139, 1141 n.1 (4th Cir. 1990) (stating, in context of Rule 12(b)(1) motion to dismiss, "a district court should properly take judicial notice of its own records").

2. Littlewood and Palmieri

As noted, the original Complaint in this case was filed in the Eastern District of Pennsylvania on April 20, 2010. *See* ECF 5 at 2 (certified docket sheet from E.D. Pa.). The complaint in *Littlewood* was filed in this district four days earlier, on April 16, 2010, and so *Littlewood* was already "pending" when this case began.[11] 31 U.S.C. § 3730(b)(5). Defendants contend that this case is "a related action based on the facts underlying" *Littlewood*, *id.*, and thus is barred by the first-to-file rule.

[11] According to the docket in *Littlewood*, the complaint was not actually entered on the docket until April 20, 2010, the same day that the original Complaint in this case was filed. However, both sides agree that *Littlewood* was initiated on April 16, 2010, and the parties have not briefed the issue of whether a case is considered "pending" under § 3730(b)(5) at the time it is filed with the court or, instead, at the time it is entered on the docket. Accordingly, I assume, without deciding, that a case is "pending" for purposes of the first-to-file rule as of the date that the complaint is filed with the court, regardless of when it is docketed.

Like Mr. Palmieri, the relator in *Littlewood* was a sales representative with Alpharma. And similarly, she alleged that Alpharma and its parent companies engaged in a scheme to market Flector Patch for off-label uses with the intent and effect of causing false claims to be submitted to governmental health care programs. In addition, all of the *Qui Tam* States in whose names Mr. Palmieri brings this litigation were also plaintiffs in *Littlewood*.

"[E]very court of appeals to consider" the meaning of the statutory phrase "'a related action based on the facts underlying [a] pending action'" in § 3730(b)(5) has construed it to mean an action based on the same "*material* facts" or the same "essential facts" as the pending action, rather than "identical facts." *Chovanec*, *supra*, 606 F.3d at 363 (quoting statute) (collecting cases) (emphasis in original). Moreover, the "circuits that have addressed this subject understand the 'material' or essential' facts to be those on which the original relator is entitled to compensation if the suit prevails." *Id.* Without detailing the allegations in *Littlewood*, suffice it to say that there is substantial overlap between the material facts alleged there and those alleged here. Both suits charge essentially the same fraudulent scheme to promote Flector Patch.

Nevertheless, Mr. Palmieri contends that the first-to-file rule should not bar this suit because, although *Littlewood* was pending at the time this suit began, it is no longer pending.[12] After the United States completed its investigation in *Littlewood*, it declined to intervene, and the relator chose not to exercise her right to litigate the suit on her own. Accordingly, the *Littlewood*

[12] Mr. Palmieri also argues that, unlike this suit, *Littlewood* contained no allegations that defendants violated the Anti-Kickback Statute. Therefore, he insists that, even if the remainder of his suit is jurisdictionally barred by the first-to-file rule, the Court should permit his claims based on the Anti-Kickback Statute to proceed. In light of my resolution of the Motion on other grounds, discussed *infra*, I need not resolve whether the kickback allegations are sufficiently distinct from the claims in *Littlewood* to evade the first-to-file bar.

action was voluntarily dismissed, without prejudice, on August 17, 2011. *See United States ex rel. Littlewood v. King Pharm., Inc.*, 806 F. Supp. 2d 833, 834-35 n.1 (D. Md. 2011).[13]

Defendants counter that, by the plain text of 31 U.S.C. § 3730(b)(5), the first-to-file rule applies at the time when a second relator "bring[s]" an action that is related to a pending *qui tam* case. Therefore, they reason that, "[b]ecause '[t]he jurisdiction of the Court depends upon the state of things at the time of the action brought,' a court determines whether the first-to-file rule bars a *qui tam* action 'by looking at the facts as they existed at the time that action was brought.'" Reply at 4 (quoting *Grynberg, supra*, 390 F.3d at 1279).

Precedent uniformly supports the view that the subsequent dismissal of a first-filed *qui tam* action, without more, cannot cure the filing of a second *qui tam* action while the first action was pending. *See, e.g.*, *Walburn, supra*, 431 F.3d at 972 n.5 ("[T]he ultimate fate of an earlier-filed action does not determine whether it bars a later action under § 3730(b)(5); rather, the question is only whether the earlier action was 'pending' at the time the later action was filed."); *United States ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1188 (9th Cir. 2001) ("To hold that a later dismissed action was not a then-pending action would be contrary to the plain language of the statute and the legislative intent."). Therefore, if the only change in the status quo since the filing of the original Complaint had been the dismissal of *Littlewood*, I would agree that the first-to-file rule would bar this suit.

However, a subsequent event of jurisdictional significance occurred: after the dismissal of *Littlewood* in August 2011, Mr. Palmieri filed his Amended Complaint on October 25, 2011.

[13] Both the United States and the relator in *Littlewood* sought to keep portions of the suit under seal, despite the United States' decision not to intervene and the dismissal of the suit, resulting in the issuance of the above-cited reported decision, denying both parties' sealing requests.

The first-to-file bar "applies only while the initial complaint is 'pending.'" *Chovanec*, *supra*, 606 F.3d at 365. After that point, the first-to-file rule does not prevent a subsequent relator from filing a related suit, although such a suit may be barred by other doctrines, such as claim or issue preclusion or another jurisdictional FCA doctrine, the public disclosure bar, which prohibits a *qui tam* suit based on information that has been publicly disclosed, unless the relator is an "original source" of the information. *See id.* at 362, 365 (citing 31 U.S.C. § 3730(e)(4)).

In *Chovanec*, the Seventh Circuit approved the district court's dismissal of a *qui tam* suit on the basis of the first-to-file bar, but held that the dismissal should have been without prejudice. Writing for the appellate court, Chief Judge Easterbrook said that, because the first-filed *qui tam* action was "no longer pending . . . [the relator] is entitled to file a new *qui tam* complaint—entitled, that is, as far as § 3730(b)(5) goes. . . . [B]ecause Chovanec may be able to frame a new complaint that would survive a motion to dismiss . . . the current proceeding should have been dismissed without prejudice." *Id.* at 365. Indeed, as Mr. Palmieri points out, on remand the district court in *Chovanec* permitted the relator to file an amended complaint, in lieu of dismissal of the suit. *See* Ex.A to Opposition (ECF 71-1).

Similarly, in *Batiste*, *supra*, 659 F.3d 1204, the D.C. Circuit upheld a district court's dismissal of a second relator's complaint under the first-to-file rule, despite the fact that the first-filed suit had been dismissed. As a fallback argument, the second relator argued that his suit should have been dismissed without prejudice, "implying that [the second relator] would like the opportunity to amend his complaint and bring th[e] case again." *Id.* at 1211. The D.C. Circuit held that this argument was "waived," observing that the first suit had been "dismissed eighteen months prior to the *Batiste* dismissal," and faulting the second relator because, "[d]uring that

time," he "never asked for leave to amend his complaint in the district court," thereby suggesting that the filing of an amended complaint could have cured the defect. *Id.*

The Tenth Circuit's discussion in *In re Natural Gas Royalties*, *supra*, 566 F.3d at 964, is also salient:

> If the first-to-file bar had been meant simply as a more draconian public disclosure bar, Congress would not have limited it to "pending" actions. While filing the complaint might put the government on notice, and while the government might remain on notice while the action is pending, the government does not cease to be on notice when a relator withdraws his claim or a court dismisses it. And yet, if that prior claim is no longer pending, the first-to-file bar no longer applies. The "pending" requirement much more effectively vindicates the goal of encouraging relators to file; it protects the potential award of a relator while his claim remains viable, but, when he drops his action another relator who qualifies as an original source may pursue his own.

Defendants cite two district court decisions in support of their argument for dismissal. *See United States ex rel. Carter v. Halliburton Co.*, No. 1:11cv602, 2011 WL 6178878 (E.D. Va. Dec. 12, 2011); *United States ex rel. Branch Consultants, LLC v. Allstate Ins. Co.*, 782 F. Supp. 2d 248 (E.D. La. 2011). *Carter* is readily distinguishable: the prior *qui tam* case that barred *Carter* was dismissed before the *Carter* Court ruled and, unlike Mr. Palmieri here, the relator had not filed an amended complaint in the interim. *See Carter*, 2011 WL 6178878, at *8. *Branch Consultants* is more closely on point. There, the court expressly ruled that an amended *qui tam* complaint could not cure a first-to-file defect in the original complaint. However, I find more persuasive the discussion of this issue in the appellate cases of *Chovanec*, *Batiste*, and *In re Natural Gas Royalties*, which grounded their analysis in the first-to-file rule's textual limitation to "pending" cases.

It is also noteworthy that the Supreme Court, in a False Claims Act case (although not in the context of the first-to-file rule), has indicated that an amended complaint is jurisdictionally

relevant. In *Rockwell International Corp. v. United States*, 549 U.S. 457 (2007), the Court held that an amended complaint had to satisfy the jurisdictional requirement that a *qui tam* claim not be based on publicly disclosed material unless the relator is an original source, regardless of whether the original complaint had cleared the public disclosure bar. The Court said that, "when a plaintiff files a complaint in federal court and then voluntarily amends the complaint, courts look to the amended complaint to determine jurisdiction." *Id*. at 473-74. It added: "The rule that subject-matter jurisdiction 'depends on the state of things at the time of the action brought,' does not suggest a different interpretation." *Id.* at 473 (internal citation omitted).

In sum, the relator here filed an Amended Complaint, at a time when the prior *qui tam* suit was no longer pending. If the Court were to dismiss the Amended Complaint, it would do so without prejudice, and the first-to-file rule would not preclude Mr. Palmieri from filing an identical pleading under a new case number tomorrow, as *Chovanec* and *In re Natural Gas Royalties* make clear.[14] It would elevate form over substance to dismiss the Amended Complaint

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[14] Defendants suggest that "it is highly doubtful that Relator Palmieri could establish himself as an original source," so as to defeat the public disclosure bar in such a hypothetical new case. Reply at 12. Maybe so. To be sure, the *Chovanec* Court noted that the public disclosure bar will often bar second-filed *qui tam* suits even when the first-to-file bar does not. *See Chovanec*, 606 F.3d at 365. However, defendants have not further developed their speculative argument concerning the public disclosure bar, nor have they advanced the public disclosure bar as a basis to dismiss the Amended Complaint itself. It is by no means obvious to the Court that Palmieri would not qualify as an original source. Indeed, he is a longstanding employee of defendants and filed his suit contemporaneously with *Littlewood*, at a time when *Littlewood* was under seal. Accordingly, I decline to dismiss this suit on the basis of defendants' unsupported speculation with respect to the public disclosure bar.

Another potential pitfall for a second-filed *qui tam* suit that survives the first-to-file bar is the doctrine of claim or issue preclusion. The *Chovanec* Court said, *id.* at 362:

> [I]f [a second-filed *qui tam*] action is related to and based on the facts of an earlier suit, then it often cannot be refiled—for, once the initial suit is resolved and a judgment entered (on the merits or by settlement), the doctrine of claim

on first-to-file grounds at this juncture. Accordingly, I conclude that the first-to-file rule does not bar Mr. Palmieri's Amended Complaint.

B. Failure to Allege Fraud with Particularity

In defendants' second challenge, they assert that the Amended Complaint fails to state a claim upon which relief can be granted. Their argument arises under Rule 12(b)(6) of the Federal Rules of Civil Procedure, and implicates the pleading standard for all civil actions under Fed. R. Civ. P. 8, as well as the heightened standard for fraud claims under Fed. R. Civ. P. 9(b).

1. Standard of Review

In the first instance, whether a complaint states a claim for relief is judged by reference to the pleading requirements of Fed. R. Civ. P. 8(a)(2). It provides that a complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." The purpose of the Rule is to provide the defendant with "fair notice" of the claim and the "grounds" for entitlement to relief. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555-56 n.3 (2007).

A plaintiff need not include "detailed factual allegations" in order to satisfy Rule 8(a)(2). *Id.* at 555. But, the Rule demands more than bald accusations or mere speculation. *Id.* To satisfy the minimal requirements of Rule 8(a)(2), the complaint must set forth "enough factual matter (taken as true) to suggest" a cognizable cause of action, "even if . . . [the] actual proof of those facts is improbable and . . . recovery is very remote and unlikely." *Id.* at 556. A complaint

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> preclusion may block any later litigation. The plaintiff in a *qui tam* action, after all, is the United States rather than the relator; whether the United States wins or loses in the initial action, that is the end of the dispute. Only when the initial action concludes without prejudice (or covers a different transaction) will a later suit—by the original relator, a different relator, or the Department of Justice—be permissible.

Preclusion doctrine does not foreclose Mr. Palmieri's suit because *Littlewood* was dismissed without prejudice. *See Littlewood*, 806 F. Supp. 2d at 834-35 n.1.

that provides no more than "labels and conclusions," or "a formulaic recitation of the elements of a cause of action," is insufficient. *Id.* at 555.

A defendant may test the adequacy of a complaint by way of a motion to dismiss under Rule 12(b)(6). *See, e.g.*, *Davani v. Va. Dept. of Transp.*, 434 F.3d 712, 720 (4th Cir. 2006). Both *Twombly*, 550 U.S. 544, and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), make clear that, in order to survive a motion to dismiss under Rule 12(b)(6), a complaint must contain facts sufficient to "state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570; *see Iqbal*, 556 U.S. at 684 ("Our decision in Twombly expounded the pleading standard for 'all civil actions'. . . ."); *see also Simmons v. United Mortgage and Loan Inv.*, 634 F.3d 754, 768 (4th Cir. 2011); *Andrew v. Clark*, 561 F.3d 261, 266 (4th Cir. 2009); *Giarratano v. Johnson*, 521 F.3d 298, 302 (4th Cir. 2008).

In reviewing a Rule 12(b)(6) motion, a court "'must accept as true all of the factual allegations contained in the complaint,'" and must "'draw all reasonable inferences [from those facts] in favor of the plaintiff.'" *E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc.*, 637 F.3d 435, 440 (4th Cir. 2011) (citations omitted). A motion pursuant to Rule 12(b)(6) typically "does not resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses," *Edwards v. City of Goldsboro*, 178 F.3d 231, 243 (4th Cir.1999) (internal quotation marks omitted), unless such a defense can be resolved on the basis of the facts alleged in the complaint. Moreover, the court is not required to accept legal conclusions drawn from the facts. *See Papasan v. Allain*, 478 U.S. 265, 286 (1986); *Monroe v. City of Charlottesville*, 579 F.3d 380, 385-86 (4th Cir. 2009), *cert. denied*, 130 S.Ct. 1740 (2010). If the "well-pleaded facts do not

permit the court to infer more than the mere possibility of misconduct," the complaint has not shown that "'the pleader is entitled to relief.'" *Iqbal*, 556 U.S. at 679 (citation omitted).

"Ordinarily, a court may not consider any documents that are outside of the complaint, or not expressly incorporated therein, on a motion to dismiss" under Rule 12(b)(6). *Clatterbuck v. City of Charlottesville*, ___ F.3d ___, No. 12-1149, slip op. at 13, 2013 WL 632950 (4th Cir. Feb. 21, 2013). In considering a Rule 12(b)(6) dismissal, however, the court may properly consider documents "attached or incorporated into the complaint," as well as documents attached to the motion to dismiss, "so long as they are integral to the complaint and authentic." *Philips v. Pitt County Memorial Hosp.*, 572 F.3d 176, 180 (4th Cir. 2009); *see also E.I. du Pont de Nemours & Co.*, 637 F.3d at 448.

Suits brought under the False Claims Act sound in fraud, and thus are "subject to Federal Rule of Civil Procedure 9(b), which requires that claimants plead fraud with particularity." *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 783-84 (4th Cir. 1999). In addition, "Rule 9(b)'s heightened pleading standard applies to state law fraud claims asserted in federal court." *N. Am. Catholic Educ. Programming Found., Inc. v. Cardinale*, 567 F.3d 8, 13 (1st Cir. 2009). Therefore, a Rule 9(b) analysis governs the relator's state law *qui tam* claims as well as his claims under the FCA.

Rule 9(b) states: "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Under the rule, a plaintiff alleging claims that sound in fraud "'must, at a minimum, describe the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained

thereby.'" *United States ex rel. Owens v. First Kuwaiti Gen'l Trading & Contracting Co.*, 612 F.3d 724, 731 (4th Cir. 2010) (citation omitted); *see also Harrison*, 176 F.3d at 784. In other words, "'Rule 9(b) requires plaintiffs to plead the who, what, when, where, and how: the first paragraph of any newspaper story.'" *Crest Construction II, Inc. v. Doe*, 660 F.3d 346, 353 (8th Cir. 2011) (citation omitted).

Rule 9(b) serves several salutary purposes:

> "First, the rule ensures that the defendant has sufficient information to formulate a defense by putting it on notice of the conduct complained of. . . . Second, Rule 9(b) exists to protect defendants from frivolous suits. A third reason for the rule is to eliminate fraud actions in which all the facts are learned after discovery. Finally, Rule 9(b) protects defendants from harm to their goodwill and reputation."

Harrison, 176 F.3d at 784 (citation omitted). Nevertheless, a "court should hesitate to dismiss a complaint under Rule 9(b) if the court is satisfied (1) that the defendant has been made aware of the particular circumstances for which she will have to prepare a defense at trial, and (2) that plaintiff has substantial prediscovery evidence of those facts." *Id.*

2. Pleading of Particular False Claims

Defendants contend that the relator's Amended Complaint does not pass muster under Rule 12(b)(6) because it fails to allege any particular instance in which a false claim was submitted to the government. To be sure, the Amended Complaint is replete with details of the marketing scheme allegedly perpetrated by defendants. But, the relator has not alleged the details of the submission of any Flector Patch prescription to a government entity for payment. Rather, as noted, the relator relies on the inference that, given defendants' alleged unlawful scheme to market Flector Patch and the contemporaneous governmental expenditures on Flector Patch prescriptions, some prescriptions caused by the fraudulent scheme must be among the

prescriptions that were reimbursed from government coffers. Defendants maintain that a *qui tam* relator must allege the "who, what, when, where, and how" required by Rule 9(b) with respect to the specific false claims that the relator alleges were submitted to the government, and must specify how a defendant "caused" such claims to be submitted, within the meaning of the FCA. In contrast, Mr. Palmieri argues that, so long as the specifics of the defendants' actions are adequately alleged under the Rule 9(b) standard, the pleading of the actual fraudulent submissions resulting from those actions may be more general.

In their briefing, the parties have sought to have this Court take a side in an emerging circuit split on this issue. Defendants rely primarily on *United States ex rel. Clausen v. Laboratory Corporation of America, Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002), *cert. denied*, 537 U.S. 1105 (2003), in which the Eleventh Circuit held:

> Rule 9(b)'s directive that 'the circumstances constituting fraud or mistake shall be stated with particularity' does not permit a False Claims Act plaintiff merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government.

In contrast, Mr. Palmieri relies on several federal appellate decisions that have expressed a more lenient pleading standard. *See, e.g., Duxbury, supra*, 579 F.3d at 29 (stating that "a relator could satisfy Rule 9(b) by providing 'factual or statistical evidence to strengthen the inference of fraud beyond possibility' without necessarily providing details as to each false claim") (citation omitted); *United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 854 (7th Cir. 2009) ("Since a relator is unlikely to have [billing] documents unless he works in the defendant's accounting department, [a requirement to allege specific false claims] takes a big bite out of *qui tam* litigation. . . . [M]uch knowledge is inferential . . . and the inference that [the

relator] proposes is a plausible one."); *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009) (holding that a complaint that does not allege "details of an actually submitted false claim, may nevertheless survive by alleging particular detains of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted").

I need not extensively review the appellate decisions on either side of the split or conduct an independent evaluation of their merits because, after briefing of this case was completed, the Fourth Circuit chose a side in the controversy.[15] In *United States ex rel. Nathan v. Takeda Pharmaceuticals of North America, Inc.*, ___ F.3d ___, No. 11-2077, 2013 WL 136030 (4th Cir. Jan. 11, 2013), a case strikingly similar to this one, the Fourth Circuit expressly adopted the position staked out by the Eleventh Circuit in *Clausen*.[16]

As in this case, the relator in *Nathan* alleged a false claim violation arising out of a scheme to promote a prescription drug for off-label use. The alleged marketing scheme for Kapidex, the drug at issue in *Nathan*, was remarkably similar to the scheme to promote Flector Patch alleged here: "The identified marketing practices were: (1) Takeda's promotion of Kapidex to rheumatologists, who typically do not treat patients having conditions for which Kapidex has

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[15] In their briefing, defendants suggested that Fourth Circuit precedent was already aligned with the Eleventh Circuit's decision in *Clausen*, but for this proposition, they cited only district court decisions. District court decisions cannot establish circuit precedent because "'[a] decision of a federal district court judge is not binding precedent in either a different judicial district, the same judicial district, or even upon the same judge in a different case.'" *Camreta v. Greene*, ___ U.S. ___, 131 S. Ct. 2020, 2033 n.7 (2011) (citation omitted).

[16] Both sides mentioned the district court decision in *Nathan*, *see* No. 1:09-cv-1086, 2011 WL 3911095 (E.D. Va. Sept. 6, 2011), in their briefing, although the relator merely asserted that this case was unlike *Nathan*, without explaining the reasons for his assertion. *See* Opposition at 27. In any event, neither side submitted a notice of recent authority to inform the Court of the Fourth Circuit's decision in *Nathan*, which is directly on point.

been approved; and (2) Takeda's practice of marketing high doses of Kapidex for the treatment of conditions for which only a lower dose has been approved by the FDA." *Nathan*, slip op. at 4. The district court dismissed the claim, and the Fourth Circuit affirmed.

The Fourth Circuit said that "the critical question is whether the defendant caused a false claim to be presented to the government, because liability under the [False Claims] Act attaches only to a claim actually presented to the government for payment, not to the underlying fraudulent scheme." *Id.*, slip op. at 8. Citing *Clausen*, the *Nathan* Court continued: "Therefore, when a relator fails to plead plausible allegations of presentment, the relator has not alleged all the elements of a claim under the Act." *Id.* The Court left no doubt as to its considered agreement with *Clausen*, *id.*:

> We agree with the Eleventh Circuit's observation that the particularity requirement of Rule 9(b) "does not permit a False Claims Act plaintiff merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government." [*Clausen*, 290 F.3d] at 1311. Rather, Rule 9(b) requires that "some indicia of reliability" must be provided in the complaint to support the allegation that an actual false claim was presented to the government. *Id.* Indeed, without such plausible allegations of presentment, a relator not only fails to meet the particularity requirement of Rule 9(b), but also does not satisfy the general plausibility standard of *Iqbal*. *See Clausen*, 290 F.3d at 1313 ("If Rule 9(b) is to carry any water, it must mean that an essential allegation and circumstance of fraudulent conduct cannot be alleged in such conclusory fashion.") . . . .

Rejecting the contrary views of other circuits, the Court said: "To the extent that other cases apply a more relaxed construction of Rule 9(b) in such circumstances, we disagree with that approach." *Id.*, slip op. at 10. Encapsulating its holding, the *Nathan* Court said: "[W]hen a defendant's actions, as alleged and as reasonably inferred from the allegations, *could* have led, but *need not necessarily* have led, to the submission of false claims, a relator must allege with

particularity that specific false claims actually were presented to the government for payment." *Id.*, slip op. at 9-10 (emphasis in original). To be sure, the Court cautioned that whether the "factual allegations in a given case meet the required standard must be evaluated on a case-specific basis." *Id.*, slip op. at 10. But, the Court held that the facts alleged in *Nathan* failed to meet the standard, and that conclusion, in my view, guts Palmieri's claim.

First, the Court rejected the sufficiency of the allegation that the defendant promoted its drug to specialists who did not treat the conditions for which the drug was approved. It said: "Fatal to the claim, Relator does not allege in the amended complaint that the targeted rheumatologists wrote any off-label prescriptions that were submitted to the government for payment, a critical omission in a case brought under the [False Claims] Act." *Id.*, slip op. at 11. The same is true of Mr. Palmieri's Amended Complaint. The Court similarly concluded that allegations of promoting excessive dosages were insufficient, because the fact that a prescription for a large dose was written "would not itself constitute a plausible allegation that the prescription was for an off-label use." *Id.*, slip op. at 13.

If anything, the complaint in *Nathan* was more detailed than the Amended Complaint here, because the relator in *Nathan* actually identified two physicians "who averred that they prescribed 60 mg dosages of Kapidex to treat [a particular condition] in Medicare patients and were unaware that the drug was available in a 30 mg dosage due to Takeda's sampling practices." *Id.*, slip op. at 14. Mr. Palmieri's Amended Complaint does not contain any such specific allegation that a particular physician prescribed Flector Patch to Medicare or Medicaid patients. Yet, even such an allegation in *Nathan* was not specific enough, according to the Fourth Circuit. It said, *id.*, slip op. at 14-15 (internal citation omitted) (emphasis added):

> [T]he amended complaint does not include any details about the particular prescriptions these physicians wrote for Medicare patients, such as approximate dates or patient information, nor does the amended complaint contain allegations that the Medicare patients ever "filled" these prescriptions or that corresponding claims for reimbursement ever were submitted to the government.
>
> As previously discussed, *liability under the Act attaches only to false claims actually submitted to the government for reimbursement*. General allegations such as those made here, that unidentified Medicare patients received prescriptions for off-label uses, do not identify with particularity any claims that would trigger liability under the Act. In the absence of the required specific allegations, *a court is unable to infer that a Medicare patient who has received a prescription for an off-label use actually filled the prescription and sought reimbursement from the government.* Indeed, "[i]t may be that physicians prescribed [the drug] for off-label uses only where the patients paid for it themselves or when the patients' private insurers paid for it." *We therefore disagree with Relator's assertion that, if a patient is insured under a government program, we reasonably may infer that any prescription the patient received for an off-label use was filled and that a claim was presented to the government*.

I recognize that, unlike this case, *Nathan* apparently did not involve allegations of violations of the Anti-Kickback Statute. However, Mr. Palmieri's charges concerning the Anti-Kickback Statute suffer from the same fatal flaw as his other *qui tam* allegations: although the relator alleges an illegal scheme that could have resulted in the submission of false claims to the government, he does not provide details of any false claim that actually was submitted.

In sum, *Nathan* is binding circuit precedent that is completely dispositive of the issue. It dictates that the Amended Complaint must be dismissed for failure to state a claim upon which relief can be granted.[17]

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[17] Like the defendants here, the defendant in *Nathan* had also argued that the relator failed to state a plausible claim of causation. In other words, in addition to arguing that the relator did not sufficiently allege the *submission* of false claims, the defendant in *Nathan* argued that the relator failed to state a plausible claim that the defendant *caused* such submissions. In light of its conclusion that the relator failed to allege sufficiently that any false claims were presented, the Fourth Circuit did "not reach the additional question whether Relator alleged sufficient facts to support the required causation element for a claim asserted under the Act."

C. With or Without Prejudice

Defendants urge dismissal with prejudice. In contrast, Mr. Palmieri asks that, in the event suit is dismissed, it should be without prejudice and with leave to amend.

Fed. R. Civ. P. 15(a)(2) provides that leave to amend should freely be given when justice so requires. It seems doubtful that Mr. Palmieri could possess sufficient information to plead actual instances when false claims were submitted to government entities as a result of the scheme he alleges. For one thing, if Mr. Palmieri had such information, there is no reason he would have withheld it. For another, by the nature of the scheme alleged, it is doubtful that such information would be in Mr. Palmieri's possession—the false claims themselves would have been submitted by patients, or at best by their physicians, but not by anyone in defendants' employ.

Nevertheless, defendants' arguments for summary dismissal with prejudice are unconvincing. This is the first occasion on which the sufficiency of Mr. Palmieri's allegations has been challenged, and he did not previously have the benefit of the Fourth Circuit's guidance in *Nathan*. No discovery has yet occurred. Although defendants point out that the United States has twice declined to prosecute the relator's allegations, that fact is immaterial. "The government's decision not to intervene in an FCA action does not mean that the government believes the claims are without merit, and the government's decision not to intervene therefore is not relevant in an FCA action brought by a private party." *United States ex rel. Ubl v. IIF Data Solutions*, 650 F.3d 445, 457 (4th Cir. 2011) (internal citation omitted). "Given its limited time and resources, the government cannot intervene in every FCA action, nor can the government

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Nathan, slip op. at 5. For the same reason, I also need not reach defendants' arguments as to causation here.

pursue every meritorious FCA claim." *Id.* Moreover, the FCA expressly contemplates that relators may pursue recovery on behalf of the government even where the government chooses not to intervene. Indeed, "[i]f the United States declines to intervene and the qui tam relator recovers proceeds under the FCA, the qui tam relator's proceeds are larger than in a case where the United States intervened." *ACLU*, *supra*, 673 F.3d at 251 (comparing relator's entitlement to 15-25% of proceeds where government intervenes with relator's entitlement to 25-30% of proceeds where government does not).[18]

I am mindful of the liberal standard for amendment of pleadings under Rule 15(a)(2). Even if it is unlikely that Mr. Palmieri will successfully be able to amend his complaint to state a cognizable claim, dismissal without prejudice is not appropriate at this juncture. Therefore, I will dismiss the Amended Complaint without prejudice and with leave to amend within 28 days. If no timely second amended complaint is filed, however, the dismissal will be with prejudice. *See Choice Hotels Int'l, Inc. v. Goodwin & Boone*, 11 F.3d 469, 471 (4th Cir. 1993) (stating that a district court is entitled to "dismiss the plaintiff's action without prejudice but with conditions that the plaintiff must satisfy, and to specify that the dismissal will become prejudicial if the plaintiff fails to satisfy the conditions," so long as the "district court's specification [is] explicit and clear").[19] An Order implementing my ruling follows.

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[18] It is noteworthy that King and Alpharma entered into a settlement agreement with the United States to resolve a *qui tam* action concerning a similar alleged marketing scheme with respect to another prescription drug, Kadian. *See* Ex.B. to Opposition (ECF 71-2).

[19] This 28-day period for amendment will also allow the United States an opportunity, in light of the Court's determination under Rule 9(b), to "intervene . . . upon a showing of good cause," 31 U.S.C. § 3130(c)(3), (or for any of the *Qui Tam* States to do so under analogous provisions of their state *qui tam* statutes), as is their right, despite having previously declined to prosecute the suit.

Date: March 5, 2013

/s/
Ellen Lipton Hollander
United States District Judge